DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-957/S-007
NDA 19-957/S-009

GlaxoSmithKline
Attention: Janice P. McKellar
Associate Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, North Carolina 22709-3398

Dear Ms. McKellar:

Please refer to your supplemental new drug applications dated July 9, 1998, S-007, received July 10, 1998, and August 27, 1999, S-009, received August 30, 1999, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Cutivate (fluticasone propionate) Ointment.

We acknowledge receipt of your submission to S-007, dated December 20, 2000 and your submissions to S-009, dated August 28, 2000 and May 23, 2001.

These supplemental new drug applications provide for the use of Cutivate (fluticasone propionate) Ointment, 0.005% for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert) submitted December 20, 2000 for S-007 and May 23, 2001 for S-009.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-957/S-007 and S-009." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonathan Wilkin

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